# Biological Product and HCT/P Deviation Reports –

Annual Summary for Fiscal Year 2015

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## I. Summary:

FDA requires reporting of certain deviations and unexpected events in manufacturing in accordance with 21 CFR 600.14, 606.171 or 1271.350(b). The following manufacturers, who had control over the product when a deviation or unexpected event occurred are required to submit Biological Product Deviation (BPD) reports to the Center for Biologics Evaluation and Research (CBER), if the safety, purity, or potency of a distributed product may be affected:

- Manufacturers of licensed biological products other than blood and blood components (licensed non-blood) who hold the biological product license [21 CFR 600.14];
- Licensed manufacturers of blood and blood components, including Source Plasma [21 CFR 606.171];
- Unlicensed registered blood establishments [21 CFR 606.171]; and
- Transfusion services [21 CFR 606.171].

The following are required to submit deviation reports to CBER, if the deviation or unexpected event involving a distributed product is related to a Core Current Good Tissue Practice requirement [21 CFR 1271.150(b)] and related to the prevention of communicable disease transmission or HCT/P contamination:

- Manufacturers of nonreproductive Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) regulated by FDA solely under section 361 of the Public Health Service Act and 21 CFR Part 1271 [21 CFR 1271.350(b)],

Detailed information concerning deviation reporting, including guidance documents on BPD reporting for blood and plasma establishments (Ref. 1) and licensed manufacturers of biological products other than blood and blood components (Ref. 2), is available at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/default.htm. A draft guidance for deviation reporting for 361 HCT/Ps (Ref. 3) was published in December 2015, and may be found at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/default.htm

This annual summary report provides an overview of the reports we received during the fiscal year, including detailed information regarding the number and types of deviation reports received. We provide combined data received over the last three fiscal years in an effort to compare data and highlight changes. Throughout the analysis, we report numbers from past reports, calculate changes, or consider aggregate counts from multiple BPD codes. These data may or may not be included in accompanying tables. Detailed counts for all BPD codes can be found in the attachments and past summary reports are available at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129757.htm.

Unfortunately, our system does not collect the necessary denominator data to calculate genuine rates when evaluating possible trends. Some perspective is gained by knowing that in calendar year 2011, an estimated 17.7 million whole blood and red blood cells products plus 2.3 million apheresis platelets were collected and there were 21 million transfusions in the United States. [1] In addition, there were 26.2 million source plasma donations in 2012, 29.4 million source plasma donations in 2013, and 32.6 million source plasma donations in 2014 made in the U.S.[2]

During fiscal year 2015 (hereafter FY15), October 1, 2014, through September 30, 2015, CBER's Office of Compliance and Biologics Quality/Division of Inspections and Surveillance entered 46,587 deviation reports into the BPD database (Table 1):

- We received more than 46,587 reports, but this summary does not capture data for reports that did not meet the reporting threshold. We notified the reporter when a report was not required.
- There was a 7.9% (4,011 reports) decrease in the number of reports we received in FY15 compared to FY14 (Table 2).
    - Blood and plasma establishments submitted 3,926 fewer reports in FY15 compared to FY14 (Table 2).
        - Licensed blood establishments submitted 2,773 fewer reports in FY15.
        - Unlicensed registered blood establishments submitted 388 fewer reports in FY15.
        - Transfusion services submitted 91 more reports in FY15.
        - Licensed plasma establishments submitted 856 fewer reports in FY15.
    - Manufacturers of licensed biological products other than blood and blood components submitted 40 fewer reports in FY15 compared to FY14 (Table 2).
        - Allergenic manufacturers submitted five fewer reports in FY15
        - Blood derivative manufacturers submitted 14 more reports in FY15.
        - Licensed in-vitro diagnostic manufacturers submitted 17 fewer reports in FY15.
        - Vaccine manufacturers submitted 24 fewer reports in FY15.
        - Licensed HCT/P manufacturers (351 HCT/P) submitted eight fewer reports in FY15.
    - 361 HCT/P manufacturers submitted 45 fewer reports in FY15 compared to FY14 (Table 2).
        - Cellular HCT/P manufacturers submitted 12 fewer reports in FY15.
        - Tissue HCT/P manufacturers submitted 33 fewer reports in FY15.

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[1] Report of the US Department of Health and Human Services. The 2011 national blood collection and utilization survey report. Washington, DC: US Department of Health and Human Services, Office of the Assistant Secretary of Health. http://www.hhs.gov/ash/bloodsafety/nbcus/index.html NOTE: the most current data was not available at the time this report was compiled.

[2] Plasma Protein Therapeutics Association at http://pptaglobal.org/plasma/plasma-collection

- The total number of reporting establishments increased from 1,832 in FY14 to 1,907 in FY15 (Table 2).
    - Compared to FY14, there were nine more licensed blood establishments, 16 more unlicensed blood establishments, 20 more transfusion services and 39 more licensed plasma establishments reporting in FY15.
    - Compared to FY14, there was one more allergenic manufacturer, one less blood derivative manufacturer, two fewer in-vitro diagnostic manufacturers, one more 351 HCT/P manufacturer, and the same number of vaccine manufacturers reporting in FY15.
    - Compared to FY14, there were 8 fewer 361 HCT/P manufacturers reporting in FY15.

Each firm responsible for reporting biological product deviations should use this information in evaluating their own deviation management program.

You may submit questions concerning this summary to:
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

You may also contact us by email at bp_deviations@fda.hhs.gov, hctp_deviations@fda.hhs.gov, or sharon.ocallaghan@fda.hhs.gov (Sharon O'Callaghan).

# Total Deviation Reports
# FY15

| Establishment Type | Number Of Reporting Establishments | Total Reports Received | *Potential* Recalls[3] | |
|---|---|---|---|---|
| | | | #Reports | % *Potential* Recall |
| **Blood/Plasma Manufacturers** | | | | |
| Licensed Blood Establishments | 219(96*) | 18,660 | 486 | 2.6% |
| Unlicensed Blood Establishments[1] | 388 | 3,093 | 14 | 0.5% |
| Transfusion Services[2] | 669 | 1,826 | 2 | 0.1% |
| Licensed Plasma Establishments | 462(21*) | 22,194 | 67 | 0.3% |
| *Sub-Total* | *1,738* | *45,773* | *569* | 1.2% |
| **Licensed Non-Blood Manufacturers** | | | | |
| Allergenic | 9(9*) | 82 | 4 | 4.9% |
| Blood Derivative | 25(20*) | 123 | 1 | 0.8% |
| In Vitro Diagnostic | 9(9*) | 111 | 4 | 3.6% |
| Vaccine | 24(18*) | 223 | 2 | 0.9% |
| 351 HCT/P | 5(3*) | 19 | 0 | 0.0% |
| *Sub-Total* | *72(59*)* | *558* | *11* | 2.0% |
| **361 HCT/P Manufacturers** | | | | |
| Cellular HCT/P | 47 | 134 | 0 | 0% |
| Tissue HCT/P | 50 | 122 | 25 | 20.5% |
| *Sub-Total* | *97* | *256* | *25* | 9.8% |
| **Total** | **1,907** | **46,587** | **605** | **1.3%** |

Table 1

[1]Unlicensed Blood Establishments – unlicensed blood establishments that perform manufacturing of blood and blood components are required to register with FDA.

[2]Transfusion Services – blood banks that perform limited blood and blood component manufacturing (e.g. pooling, thawing, compatibility testing), may or may not register with FDA.

*****Number of license holders; one or more establishments operate under one biologics license.

[3]Percent of Potential Recalls calculated for each establishment type (#potential recalls/#total reports)

# Total Deviation Reports
# FY13 – FY15

Table 2

| Establishment Type | Number Of Reporting Establishments | | | Total Reports Received | | | *Potential* Recalls | | |
|---|---|---|---|---|---|---|---|---|---|
| **Blood/Plasma Manufacturers** | **FY13** | **FY14** | **FY15** | **FY13** | **FY14** | **FY15** | **FY13** | **FY14** | **FY15** |
| Licensed Blood Establishments | 229(109*) | 210(97*) | 219(96*) | 25,503 | 21,433 | 18,660 | 552 | 503 | 486 |
| Unlicensed Blood Establishments[1] | 387 | 372 | 388 | 3,645 | 3,481 | 3,093 | 19 | 21 | 14 |
| Transfusion Services[2] | 664 | 649 | 669 | 2,062 | 1,735 | 1,826 | 1 | 0 | 2 |
| Licensed Plasma Establishments | 405(22*) | 423(21*) | 462(21*) | 22,580 | 23,050 | 22,194 | 73 | 80 | 67 |
| *Sub-Total* | *1,685* | *1,654* | *1,738* | *53,790* | *49,699* | *45,773* | *645* | *604* | *569* |
| **Licensed Non-Blood Manufacturers** | | | | | | | | | |
| Allergenic | 6(6*) | 8(8*) | 9(9*) | 107 | 87 | 82 | 5 | 3 | 4 |
| Blood Derivative | 24(18*) | 26(21*) | 25(20*) | 93 | 109 | 123 | 3 | 1 | 1 |
| In Vitro Diagnostic | 12(12*) | 11(11*) | 9(9*) | 159 | 128 | 111 | 10 | 7 | 4 |
| Vaccine | 20(17*) | 24(18*) | 24(18*) | 223 | 247 | 223 | 2 | 3 | 2 |
| 351 HCT/P | 4(1*) | 4(2*) | 5(3*) | 34 | 27 | 19 | 0 | 1 | 0 |
| *Sub-Total* | *66(55*)* | *73(60*)* | *72(59*)* | *616* | *598* | *558* | *20* | *15* | *11* |
| **361 HCT/P Manufacturers** | | | | | | | | | |
| Cellular HCT/P | 39 | 52 | 47 | 115 | 146 | 134 | 0 | 0 | 0 |
| Tissue HCT/P | 46 | 53 | 50 | 195 | 155 | 122 | 124 | 28 | 25 |
| *Sub-Total* | *85* | *105* | *97* | *310* | *301* | *256* | *124* | *28* | *25* |
| **Total** | **1,836** | **1,832** | **1,907** | **54,716** | **50,598** | **46,587** | **789** | **647** | **605** |

[1]Unlicensed Blood Establishments – unlicensed blood establishments that perform manufacturing of blood and blood components are required to register with FDA.

[2]Transfusion Services – blood banks that perform limited blood and blood component manufacturing (e.g. pooling, thawing, compatibility testing), may or may not register with FDA.

*Number of license holders; one or more establishments operate under one biologics license.

# Blood & Plasma BPD Reports by Manufacturing System
# FY13 – FY15

Table 3

| **Manufacturing System** | **FY13** | | **FY14** | | **FY15** | |
|---|---|---|---|---|---|---|
| Donor Suitability | 41,970 | 78.0% | 37,758 | 76.0% | 34,098 | 74.5% |
| *Post Donation Information* | *38,585* | *71.7%* | *36,072* | *72.6%* | *32,729* | *71.5%* |
| *Donor Screening* | *2,871* | *5.3%* | *1,303* | *2.6%* | *1,328* | *2.9%* |
| *Donor Deferral* | *514* | *1.0%* | *383* | *0.8%* | *41* | *0.1%* |
| QC & Distribution | 4,484 | 8.3% | 4,460 | 9.0% | 4,422 | 9.7% |
| Miscellaneous | 3,257 | 6.1% | 3,749 | 7.5% | 3,680 | 8.0% |
| Labeling | 1,864 | 3.5% | 1,675 | 3.4% | 1,638 | 3.6% |
| Collection | 1,034 | *1.9%* | *953* | 1.9% | 928 | 2.0% |
| Laboratory Testing | 945 | 1.8% | 829 | 1.7% | 802 | 1.8% |
| *Routine Testing* | *939* | *1.7%* | *817* | *1.6%* | *794* | *1.7%* |
| *Viral Testing* | *6* | *0.0%* | *12* | *0.0%* | *8* | *0.0%* |
| Component Preparation | 236 | 0.4% | 275 | 0.6% | 205 | 0.4% |
| **Total** | **53,790** | **100%** | **49,699** | **100%** | **45,773** | **100%** |

# Blood & Plasma BPD Reports by Manufacturing System
# FY13 – FY15

Table 4

| Manufacturing System | Licensed Blood Establishments | | | Unlicensed Blood Establishments | | |
|---|---|---|---|---|---|---|
| | *FY13* | *FY14* | *FY15* | *FY13* | *FY14* | *FY15* |
| DS-Post Donation Information | 18,170 | 15,699 | 13,474 | 369 | 366 | 313 |
| QC & Distribution | 1,221 | 1,190 | 1,122 | 1,787 | 1,860 | 1,660 |
| Miscellaneous | 1,155 | 1,213 | 1,143 | 9 | 13 | 17 |
| Labeling | 468 | 506 | 482 | 941 | 772 | 727 |
| DS-Donor Screening | 2,621 | 1,113 | 1,158 | 54 | 45 | 25 |
| Blood Collection | 948 | 879 | 868 | 83 | 72 | 56 |
| LT-Routine Testing | 245 | 228 | 232 | 332 | 297 | 236 |
| Component Preparation | 161 | 220 | 150 | 66 | 51 | 52 |
| DS-Donor Deferral | 508 | 375 | 25 | 4 | 3 | 5 |
| LT-Viral Testing | 6 | 10 | 6 | 0 | 2 | 2 |
| **Total** | **25,503** | **21,433** | **18,660** | **3,645** | **3,481** | **3,093** |

DS-Donor Suitability
LT-Laboratory Testing

Table 4 (continued)

| Manufacturing System | Transfusion Services | | | Licensed Plasma Establishments | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | *FY13* | *FY14* | *FY15* | *FY13* | *FY14* | *FY15* | *FY13* | *FY14* | *FY15* |
| DS-Post Donation Information | NA | NA | NA | 20,046 | 20,007 | 18,942 | 38,585 | 36,072 | 32,729 |
| QC & Distribution | 1,243 | 1,043 | 1,073 | 233 | 367 | 567 | 4,484 | 4,460 | 4,422 |
| Miscellaneous | NA | NA | NA | 2,093 | 2,523 | 2,520 | 3,257 | 3,749 | 3,680 |
| Labeling | 450 | 397 | 424 | 5 | 0 | 5 | 1,864 | 1,675 | 1,638 |
| DS-Donor Screening | NA | NA | NA | 196 | 145 | 145 | 2,871 | 1,303 | 1,328 |
| Blood Collection | NA | NA | NA | 3 | 2 | 4 | 1,034 | 953 | 928 |
| LT-Routine Testing | 362 | 292 | 326 | 0 | 0 | 0 | 939 | 817 | 794 |
| Component Preparation | 7 | 3 | 3 | 2 | 1 | 0 | 236 | 275 | 205 |
| DS-Donor Deferral | NA | NA | NA | 2 | 5 | 11 | 514 | 383 | 41 |
| LT-Viral Testing | NA | NA | NA | 0 | 0 | 0 | 6 | 12 | 8 |
| **Total** | **2,062** | **1,735** | **1,826** | **22,580** | **23,050** | **22,194** | **53,790** | **49,699** | **45,773** |

DS-Donor Suitability
LT-Laboratory Testing

## Licensed Non-Blood Deviation Reports by Manufacturing System FY13 – FY15

Table 5

| Manufacturing System | Allergenic | | | Blood Derivative | | | In Vitro Diagnostic | | |
|---|---|---|---|---|---|---|---|---|---|
| | *FY13* | *FY14* | *FY15* | *FY13* | *FY14* | *FY15* | *FY13* | *FY14* | *FY15* |
| Product Specifications | 94 | 81 | 69 | 33 | 33 | 35 | 79 | 76 | 66 |
| Quality Control & Distribution | 2 | 0 | 0 | 8 | 14 | 22 | 49 | 19 | 20 |
| Testing | 0 | 1 | 4 | 8 | 14 | 23 | 5 | 2 | 3 |
| Process Controls | 0 | 0 | 2 | 23 | 31 | 27 | 4 | 12 | 3 |
| Labeling | 11 | 5 | 6 | 3 | 8 | 2 | 15 | 12 | 14 |
| Miscellaneous | 0 | 0 | 0 | 1 | 1 | 7 | 3 | 1 | 1 |
| Incoming Material | 0 | 0 | 1 | 17 | 8 | 7 | 4 | 6 | 4 |
| **Total** | **107** | **87** | **82** | **93** | **109** | **123** | **159** | **128** | **111** |

Table 5 (continued)

| Manufacturing System | Vaccine | | | 351 HCT/P | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | *FY13* | *FY14* | *FY15* | *FY13* | *FY14* | *FY15* | *FY13* | *FY14* | *FY15* |
| Product Specifications | 84 | 84 | 74 | 19 | 8 | 8 | 309 | 282 | 252 |
| Quality Control & Distribution | 41 | 48 | 30 | 0 | 1 | 0 | 100 | 82 | 72 |
| Testing | 16 | 36 | 43 | 2 | 3 | 2 | 31 | 56 | 75 |
| Process Controls | 24 | 14 | 20 | 4 | 0 | 1 | 55 | 57 | 53 |
| Labeling | 27 | 29 | 22 | 9 | 15 | 8 | 65 | 69 | 52 |
| Miscellaneous | 10 | 25 | 20 | 0 | 0 | 0 | 14 | 27 | 28 |
| Incoming Material | 21 | 11 | 14 | 0 | 0 | 0 | 42 | 25 | 26 |
| **Total** | **223** | **247** | **223** | **34** | **27** | **19** | **616** | **598** | **558** |

## 361 HCT/P Deviation Reports by Manufacturing System FY13 – FY15

Table 6

| Manufacturing System | Cellular HCT/Ps | | | Tissue HCT/Ps | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | *FY13* | *FY14* | *FY15* | *FY13* | *FY14* | *FY15* | *FY13* | *FY14* | *FY15* |
| Processing & Processing Controls | 58 | 76 | 71 | 11 | 14 | 5 | 69 | 90 | 76 |
| Receipt, Pre-Distribution, Shipment & Distribution. | 51 | 57 | 48 | 18 | 22 | 21 | 69 | 79 | 69 |
| Donor Eligibility | 1 | 1 | 0 | 29 | 61 | 39 | 30 | 62 | 39 |
| Donor Screening | 1 | 4 | 0 | 92 | 31 | 35 | 93 | 35 | 35 |
| Donor Testing | 0 | 1 | 2 | 21 | 7 | 9 | 21 | 8 | 11 |
| Recovery | 1 | 1 | 7 | 1 | 2 | 3 | 2 | 3 | 10 |
| Supplies and Reagents | 2 | 4 | 6 | 6 | 3 | 1 | 8 | 7 | 7 |
| Labeling Controls | 1 | 0 | 0 | 15 | 8 | 5 | 16 | 8 | 5 |
| Storage | 0 | 2 | 0 | 0 | 5 | 4 | 0 | 7 | 4 |
| Environmental Control | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 |
| Equipment | 0 | 0 | 0 | 2 | 1 | 0 | 2 | 1 | 0 |
| **Total** | **115** | **146** | **134** | **195** | **155** | **122** | **310** | **301** | **256** |

## II. BPD Reports Submitted by Blood and Plasma Establishments:

General Overview

Blood and plasma establishments submitted 3,926 fewer reports in FY15 than in the previous fiscal year (FY14-49,699) (Table 2).

- Licensed blood establishments submitted 2,773 fewer reports in FY15 (FY14-21,433) (Table 4).
    - The number of reports involving post donation information decreased from 15,699 in FY14 to 13,474 in FY15.
        - There were 1,180 fewer reports involving a donor who traveled to a malarial endemic area (FY14-5,317, FY15-4,137).
        - There were 317 fewer reports involving a donor who traveled to a vCJD risk area (FY14-2,628, FY15-2,311).
        - There were 278 fewer reports involving a donor who reported a history of receiving a tattoo and/or piercing (FY14-1,229, FY15-951).
        - There were 120 fewer reports involving a male donor who had sex with another male (FY14-1,025, FY15-905).
        - There were 85 fewer reports involving a donor who reported a post donation illness (FY14-970, FY15-885).
    - The number of reports involving donor screening increased from 1,113 in FY14 to 1,158 in FY15.
        - There were 85 more reports in FY15 in which the deferral screening was not done or incorrectly performed, including using the incorrect donor identification, to determine if the donor was previously deferred (FY14-590, FY15-675).
    - The number of reports involving donor deferral decreased over the past three years (FY13-508, FY14-375, FY15-25).
        - The number of reports involving donors who were missing or incorrectly identified on the deferral list, and the donor was or should have been previously deferred due to testing decreased from 90 in FY14 to 8 in FY15.
        - The number of reports involving donors who were missing or incorrectly identified on the deferral list, and the donor was or should have been previously deferred due to history decreased from 284 in FY14 to 10 in FY15.
    - The number of reports involving component preparation decreased from 220 in FY14 to 150 in FY15.
        - The number of reports involving sterile docking procedure not performed in accordance with specifications decreased from 46 in FY14 to 29 in FY15.
        - The number of reports involving additive solution not added in accordance with specifications decreased from 18 in FY14 to 6 in FY15.

- Unlicensed registered blood establishments submitted 388 fewer reports in FY15 (FY14-3,481) (Table 4).

- The number of reports involving quality control and distribution decreased from 1,860 in FY14 to 1,660 in FY15.
  - The number of reports involving distribution procedures not performed in accordance with the blood bank transfusion service's specifications decreased from 1,446 in FY14 to 1,311 in FY15.
- The number of reports involving labeling decreased from 772 in FY14 to 727 in FY15.
- The number of reports involving post donation information decreased from 366 in FY14 to 313 in FY15.
- The number of reports involving routine testing decreased from 297 in FY14 to 236 in FY15.

- Transfusion services submitted 91 more reports in FY15 (FY14-1,735) (Table 4).
  - Transfusion services typically report few BPDs and may file no reports in a given year. For example, 504 (75%) of those reporting in FY15 submitted one or two reports and only 74 (11%) transfusion services submitted more than five reports during FY15.
  - The number of reports involving quality control and distribution increased from 1,043 in FY14 to 1,073 in FY15.
  - The number of reports involving labeling increased from 397 in FY14 to 424 in FY15.
  - The number of reports involving routine testing increased from 292 in FY14 to 326 in FY15.
- Licensed plasma establishments submitted 856 fewer reports in FY15 (FY14-23,050) (Table 4).
  - The number of reports involving post donation information decreased from 20,007 in FY14 to 18,942 in FY15.

    *There was an increase in the number of reports involving a donor who:*
    - Had a positive drug screen ( FY14-865, FY15-925)
    - Had a history of incarceration (FY14-826, FY15-844)
    - Traveled to a vCJD risk area (FY14-211, FY15-258)

    *There was a decrease in the number of reports involving a donor who:*
    - Had a history of tattoo and/or piercing (FY14-13,303, FY15-12,975)
    - Had a sex partner that was reactive for HIV or Hepatitis (FY14-459, FY15-413)
      - HIV: FY14-100, FY15-91
      - HBV: FY14-100, FY15-69
      - HCV: FY14-259, FY15-253
    - Had non-sexual exposure to someone with HIV or Hepatitis (FY14-1,007, FY15-542)
      - HIV: FY14-7, FY15-5
      - HBV: FY14-220, FY15-124
      - HCV: FY14-781, FY15-413

  - The number of reports involving distributed products collected from a donor who subsequently tested confirmed positive for a viral marker was similar to the

number of reports submitted the previous year (2,523 in FY14 compared to 2,520 in FY15).
    - The number of reports in which a donor subsequently tested confirmed positive for HCV increased 2% (FY14-1,643, FY15-1,677).
    - The number of reports in which a donor subsequently tested confirmed positive for HBV decreased 12% (FY14-578, FY15-508).
    - The number of reports in which a donor subsequently tested confirmed positive for HIV increased 7% (FY14-296, FY15-316).
- The number of reports involving quality control and distribution increased 54% (FY14-367, FY15-567).
    - The number of reports in which a donor tested positive for an atypical antibody increased from 213 in FY14 to 431 in FY15.
- The number of reports involving donor screening was similar to the number of reports received in the previous year (144 in FY14 compared to 145 in FY15).

## Total BPDRs by Manufacturing System
## Blood and Plasma Establishments
## FY15

Table 7

| Manufacturing System | Licensed Blood Establishments | Unlicensed Blood Establishments | Transfusion Services | Licensed Plasma Establishments | Total | |
|---|---|---|---|---|---|---|
| DS-Post Donation Information | 13,474 | 313 | NA | 18,942 | 32,729 | 71.5% |
| QC & Distribution | 1,122 | 1,660 | 1,073 | 567 | 4,422 | 9.7% |
| Miscellaneous | 1,143 | 17 | NA | 2,520 | 3,680 | 8.0% |
| Labeling | 482 | 727 | 424 | 5 | 1,638 | 3.6% |
| DS-Donor Screening | 1,158 | 25 | NA | 145 | 1,328 | 2.9% |
| Blood Collection | 868 | 56 | NA | 4 | 928 | 2.0% |
| LT-Routine Testing | 232 | 236 | 326 | 0 | 794 | 1.7% |
| Component Preparation | 150 | 52 | 3 | 0 | 205 | 0.4% |
| DS-Donor Deferral | 25 | 5 | NA | 11 | 41 | 0.1% |
| LT-Viral Testing | 6 | 2 | NA | 0 | 8 | <0.1% |
| **Total** | **18,660** | **3,093** | **1,826** | **22,194** | **45,773** | 100% |

DS-Donor Suitability
LT-Laboratory Testing
NA-Not applicable: manufacturing not performed in transfusion service

Post Donation Information

Post donation information (PDI) continues to be the most frequently reported event associated with the manufacturing of blood and plasma products (72% of deviation reports) (Table 7). The number of reports blood and plasma establishments submitted involving post donation information decreased 9% from the previous fiscal year (FY14-36,072, FY15-32,729) (Table 4).

- Blood establishments submitted 2,278 fewer reports involving post donation information, which is a decrease of 14%, in FY15 compared to FY14 (Table 8).
    - They submitted 1,237 fewer reports involving a donor who traveled to a malarial risk area, 291 fewer reports involving a donor who traveled to a vCJD risk area, 280 fewer reports involving a donor who received a tattoo and/or piercing, and 119 fewer reports involving a male donor who had a history of sex with another male.
- Licensed plasma establishments submitted 1,065 fewer reports involving post donation information, which is a decrease of 5%, in FY15 compared to FY14 (Table 8).
    - They submitted 328 fewer reports involving donors who had a history of tattoo and/or piercing and 368 fewer reports involving donors who had a history of non-sexual exposure to Hepatitis C.
    - They submitted 60 more reports involving donors who had a positive drug screen.

Table 8 illustrates the major differences in post donation information reports from FY13 to FY15. Only the five most frequently reported categories are included in the table.

**PDI Reports Submitted by Blood and Plasma Establishments**

Table 8

| **Blood Establishments** | **FY13** | **FY14** | **FY15** |
|---|---|---|---|
| Post Donation Information (PD) – *total* | 18,539 | 16,065 | 13,787 |
| Donor had a history of travel to malarial risk area (PD1236) | 6,733 | 5,460 | 4,223 |
| Donor had a history of travel to vCJD risk area (PD1242) | 2,633 | 2,684 | 2,393 |
| Donor received tattoo and/or piercing(PD1259) | 1,402 | 1,253 | 973 |
| Donor had history of male to male sex (PD1214) | 1,319 | 1,041 | 922 |
| Post donation illness (PD1301) | 1,104 | 987 | 800 |

| **Licensed Plasma Establishments** | **FY13** | **FY14** | **FY15** |
|---|---|---|---|
| Post Donation Information (PD) – *total* | 20,046 | 20,007 | 18,942 |
| Donor received tattoo and/or piercing (PD1259) | 13,443 | 13,303 | 12,975 |
| Donor tested reactive at another center, specific testing unknown (PD1114) | 724 | 1,119 | 1,116 |
| Positive drug screen (PD1254) | 506 | 865 | 925 |
| Donor had a history of incarceration (PD1249) | 1,073 | 826 | 844 |
| Donor had a history of non-sexual exposure to Hepatitis C (PD1235) | 832 | 781 | 413 |

*Note: All post donation information reports are not included in this table.*

Miscellaneous

The total number of miscellaneous reports decreased 20% from the previous fiscal year (FY14-3,749, FY15-3,680) (Table 4). The majority of these reports involved the distribution of a unit that was collected from a donor who subsequently tested confirmed positive for a viral marker on a later donation (FY14-3,725, FY15-3,652).

- The number of these reports submitted by blood establishments decreased 6% (FY14-1,202, FY15-1,132) from the previous fiscal year (Table 9).
- The number of these reports submitted by licensed plasma establishments was similar to the number of reports submitted the previous year (2,523 in FY14 compared to 2,520 in FY15) (Table 9).

Table 9 illustrates the number of reports related to units collected from donors who subsequently tested confirmed positive for selected viral markers (lookback).

**Viral Marker Lookback Reports**
**Submitted by Blood and Plasma Establishments**

Table 9

| **Blood Establishments** | **FY11** | **FY12** | **FY13** | **FY14** | **FY15** |
|---|---|---|---|---|---|
| Lookback; Subsequent unit confirmed positive (MI02) - *total* | 830 | 927 | 1,140 | 1,202 | 1,132 |
| HBV (MI0203) | 157 | 140 | 343 | 412 | 568 |
| HCV (MI0204) | 421 | 506 | 470 | 421 | 321 |
| HIV (MI0202) | 183 | 180 | 200 | 191 | 129 |

| **Licensed Plasma Establishments** | **FY11** | **FY12** | **FY13** | **FY14** | **FY15** |
|---|---|---|---|---|---|
| Lookback; Subsequent unit confirmed positive (MI02) - *total* | 1,687 | 1,988 | 2,093 | 2,523 | 2,520 |
| HCV (MI0204) | 1,007 | 1,270 | 1,435 | 1,643 | 1,677 |
| HBV (MI0203) | 482 | 472 | 390 | 578 | 508 |
| HIV (MI0202) | 192 | 243 | 264 | 296 | 316 |

## *A. Most Frequent BPD Reports Submitted by Licensed Blood Establishments*[3]

Of the 18,660 reports (Table 7) submitted by licensed blood establishments, 13,474 (72.2%) reports involved **post donation information** (Table 10).

- The number of these reports decreased 14% (FY14-15,698).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history decreased 15% (FY14-14,624).
    - The number of reports in which a donor or third party provided subsequent information regarding male to male sex decreased 12% (FY14-1,025).
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a malaria risk area decreased 22% (FY14-5,317).
    - The number of reports in which a donor or third party provided subsequent information regarding received a tattoo and/or piercing decreased 23% (FY14-1,229).
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a vCJD risk area decreased 12% (FY14-2,630).
- The number of reports in which a donor or third party provided subsequent information related to a post donation illness decreased 9% (FY14-970).
    - The number of reports in which a donor had a fever or diarrhea post donation decreased from 484 in FY14 to 463 in FY15.
- The number of reports in which a donor or third party provided subsequent information related to the donor testing positive increased from 66 in FY14 to 115 in FY15.

[3] Licensed blood establishments do not include Source Plasma establishments, for the purpose of this summary.

## Most Frequent BPD Reports - Post Donation Information
## From *Licensed Blood Establishments*

Table 10

| POST DONATION INFORMATION 13,474 | # Reports | % of Total (PD) |
|---|---|---|
| ***Behavior/History*** | ***12,445*** | ***92.4%*** |
| Travel to malaria endemic area/history of malaria | 4,137 | 30.7% |
| Risk factors associated with Creutzfeldt-Jakob Disease (CJD) – travel | 2,311 | 17.2% |
| Donor received tattoo and/or piercing | 951 | 7.1% |
| Male donor had sex with another man | 905 | 6.7% |
| Received finasteride (Proscar or Propecia), Tegison, Accutane, Avodart, Jalyn, or Absorica | 746 | 5.5% |
| ***Illness*** | ***885*** | ***6.6%*** |
| Post donation illness (not hepatitis, HIV, HTLV-I, STD, cancer or cold/flu related) | 794 | 5.9% |
| Fever/diarrhea | 463 | 3.4% |
| Infection | 205 | 1.5% |
| Post donation diagnosis or symptoms of HIV, or reactive test for HIV | 25 | 0.2% |
| Post donation diagnosis or symptoms of Hepatitis C, or reactive test for Hepatitis C | 24 | 0.2% |
| Post donation diagnosis or symptoms of sexually transmitted disease, or reactive test for sexually transmitted disease | 15 | 0.1% |
| ***Testing**** | ***115*** | ***0.9%*** |
| Tested reactive for HIV prior to donation | 50 | 0.4% |
| Tested reactive for Hepatitis C prior to donation | 29 | 0.2% |
| Tested reactive for Hepatitis B prior to donation | 11 | 0.1% |
| Tested reactive for HTLV prior to donation | 11 | 0.1% |
| ***Not specifically related to high risk behavior*** | ***29*** | ***0.2%*** |
| Donor does not want their blood used | 16 | 0.1% |
| Donated to be tested or called back for test results | 12 | 0.1% |

*Includes testing positive for viral marker prior to donation at another location

*Note: All post donation information reports are not included in this table.*

Of the 18,660 reports (Table 7) submitted by licensed blood establishments, 1,158 (6.2%) reports involved **donor screening** deviations or unexpected events (Table 11).

- The number of these reports increased 4% (FY14-1,113).
- The number of reports in which the deferral screening was not done or incorrectly performed, including using the incorrect donor identification, to determine if the donor was previously deferred increased 14% (FY14-590).
    - 63% of these reports involve donors who were not previously deferred
- The number of reports in which the donor record was incomplete or incorrect decreased 5% (FY14-267).
    - 89% of these reports involve donor history question that were incomplete or not documented. Most of these related to asking the incorrect gender specific questions.
- The number of reports in which the donor gave a history that warranted deferral or follow up and was not deferred or follow up questions were not asked, decreased from 233 in FY14 to 208 in FY15.

**Most Frequent BPD Reports – Donor Screening**
**From *Licensed Blood Establishments***

Table 11

| DONOR SCREENING 1,158 | # Reports | % of Total (DS) |
|---|---|---|
| ***Deferral screening not done or incorrectly performed, including incorrect ID used during search*** | ***675*** | ***58.3%*** |
| Donor not previously deferred | 426 | 36.8% |
| Donor previously deferred due to history | 142 | 12.3% |
| Donor previously deferred due to testing | 107 | 9.2% |
| ***Donor record incomplete or incorrect*** | ***253*** | ***21.8%*** |
| Donor history questions | 224 | 19.3% |
| Incorrect gender specific question asked or incorrect answer | 137 | 11.8% |
| Donor identification | 16 | 1.4% |
| Donor signature missing | 6 | 0.5% |
| Arm inspection | 4 | 0.3% |
| ***Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked*** | ***208*** | ***18.0%*** |
| Travel to malaria endemic area/history of malaria | 125 | 10.8% |
| Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel | 38 | 3.3% |
| ***Donor did not meet acceptance criteria*** | ***22*** | ***1.9%*** |
| Hemoglobin or Hematocrit unacceptable or not documented or testing was performed incorrectly | 11 | 0.9% |
| Temperature unacceptable or not documented | 3 | 0.3% |

*Note: All donor screening reports are not included in this table.*

Of the 18,660 reports (Table 7) submitted by licensed blood establishments, 1,143 (6.1%) reports involved **miscellaneous** deviations or unexpected events (Table 12)**.**

- The number of these reports decreased 6% (FY14-1,213).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for a viral marker decreased 6% (FY14-1,191).
  - The number of reports in which a donor subsequently tested confirmed positive for HCV decreased from 420 in FY14 to 321 in FY15.
  - The number of reports in which a donor subsequently tested confirmed positive for HIV decreased from 187 in FY14 to 127 in FY15.
  - The number of reports in which a donor subsequently tested confirmed positive for HBV increased from 411 in FY14 to 566 in FY15.
    - The number of reports in which a donor tested repeat reactive for anti-HBc and either a second test was also repeat reactive or a second test was not performed, increased from 356 in FY14 to 504 in FY15.
- The number of reports in which a donor was either implicated in or not ruled out of a transfusion associated disease was similar to the number of reports received in the previous year (22 in FY14 compared to 26 in FY15).
  - There were four more reports received in FY15 involving Babesia (FY14-16).
  - There were three reports received in FY15 (five in FY14) in which a donor was either implicated in or not ruled out of a transfusion associated Hepatitis.
    - There was one report involving Hepatitis C received in FY15 (FY14-two).
    - There were two reports involving Hepatitis B received in FY15 (FY14-two).
    - In two cases, a donor could not be ruled out. In one case, a donor was identified as positive for HBV.

**Most Frequent BPD Reports - Miscellaneous**
**From *Licensed Blood Establishments***

Table 12

| MISCELLANEOUS (MI) 1,143 | # Reports | % of Total (MI) |
|---|---|---|
| ***Lookback; subsequent unit tested confirmed positive for:*** | ***1,117*** | ***97.7%*** |
| HBV | 566 | 49.5% |
| Anti-HBc positive | 504 | 44.1% |
| HCV | 321 | 28.1% |
| HIV | 127 | 11.1% |
| West Nile Virus | 68 | 5.9% |
| HTLV | 13 | 1.1% |
| Chagas | 11 | 1.0% |
| Babesia | 5 | 0.4% |
| ***Donor implicated in transfusion associated disease*** | ***26*** | ***2.3%*** |
| Babesia | 20 | 1.7% |
| Hepatitis B | 2 | 0.2% |
| Hepatitis C | 1 | 0.1% |

*Note: All miscellaneous reports are not included in this table.*

Of the 18,660 reports (Table 7) submitted by licensed blood establishments, 1,122 (6.0%) reports involved **quality control and distribution** deviations or unexpected events (Table 13).

- The number of these reports decreased 6% (FY14-1,190).
- The number of reports involving the distribution of a product that did not meet specifications decreased from 714 in FY14 to 623 in FY15.
    - The number of reports involving the release of a product with unacceptable, undocumented, or incomplete product QC decreased from 469 in FY14 to 405 in FY15. The number of reports related to bacterial detection testing decreased from 281 in FY14 to 238 in FY15.
- The number of reports involving shipping and storage increased from 238 in FY14 to 268 in FY15.
- The number of reports involving distribution procedures not performed in accordance with blood bank transfusion service's specification was similar to the number of reports we received in the previous year (126 in FY14 compared to 128 in FY15).

**Most Frequent BPD Reports –Quality Control & Distribution**
**From *Licensed Blood Establishments***

Table 13

| QC & DISTRIBUTION (QC) 1,122 | # Reports | % of Total (QC) |
|---|---|---|
| ***Distribution of product that did not meet specifications*** | ***623*** | ***55.5%*** |
| Product QC unacceptable, not performed, not documented, or incomplete | 405 | 36.1% |
| Bacterial detection testing | 238 | 21.2% |
| White Blood Cell count | 54 | 4.8% |
| Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or documented | 61 | 5.4% |
| Product identified as unsuitable due to a donor screening deviation or unexpected event | 36 | 3.2% |
| Product in which specification other than QC was not met | 28 | 2.5% |
| Product identified as unsuitable due to a collection deviation or unexpected event | 25 | 2.2% |
| ***Shipping and storage*** | ***268*** | ***23.9%*** |
| Product arrived at consignee at unacceptable temperature | 82 | 7.3% |
| Product not packaged in accordance with specifications or no documentation that product was packed appropriately | 55 | 4.9% |
| No documentation that product was shipped or stored at appropriate temperature | 49 | 4.4% |
| ***Distribution procedures not performed in accordance with blood bank transfusion service's specifications*** | ***128*** | ***11.4%*** |
| Product not documented or incorrectly documented as issued in the computer | 34 | 3.0% |
| Improper product selected for patient | 24 | 2.1% |
| Product not irradiated as required | 21 | 1.9% |
| ***Testing not performed, incompletely performed, or not documented*** | ***69*** | ***6.1%*** |
| Antigen screen | 16 | 1.4% |
| ABO and/or Rh | 12 | 1.1% |
| Compatibility | 12 | 1.1% |
| HLA antibodies | 12 | 1.1% |

*Note: All post donation information reports are not included in this table.*

Of the 18,660 (Table 7) reports submitted by licensed blood establishments, 868 (4.7%) reports involved **blood collection** deviations or unexpected events (Table 14)**.**

- The number of these reports decreased 5% (FY14-879).
- The number of reports involving the collection process decreased from 788 in FY14 to 779 in FY15.
    - The number of reports involving clotted units decreased from 740 in FY14 to 721 in FY15.
- The number of reports in which the sterility of a product may have been compromised was similar the number of reports we received in the previous year (71 in FY14 compared to 67 in FY15).
    - The number of reports involving bacterial contamination was similar the number of reports we received in the previous year (54 in FY14 compared to 49 in FY15).

**Most Frequent BPD Reports – Blood Collection**
**From *Licensed Blood Establishments***

Table 14

| BLOOD COLLECTION (BC) 868 | #Reports | % of Total (BC) |
|---|---|---|
| ***Collection process*** | ***779*** | ***89.7%*** |
| Product contained clots or fibrin, not discovered prior to distribution | 721 | 83.1% |
| Product hemolyzed, not discovered prior to distribution | 17 | 2.0% |
| Apheresis collection process | 11 | 1.3% |
| Donor sample tube mix-up or donor sample tube mislabeled | 10 | 1.2% |
| ***Sterility compromised*** | ***67*** | ***7.7%*** |
| Bacterial contamination | 49 | 5.6% |
| Arm prep not performed or performed inappropriately | 12 | 1.4% |
| Air contamination | 6 | 0.7% |
| ***Collection bag*** | ***21*** | ***2.4%*** |
| Potential collection set defect | 17 | 2.0% |

*Note: All blood collection reports are not included in this table.*

## *B. Most Frequent BPD Reports Submitted by Unlicensed Registered Blood Establishments*

Of the 3,093 reports (Table 7) submitted by unlicensed registered blood establishments, 1,660 (53.7%) involved **quality control and distribution** deviations or unexpected events (Table 15)**.**

- The number of these reports decreased 11% (FY14-1,860).
- The number of reports involving distribution procedures not performed in accordance with the blood bank transfusion service's specifications decreased 9% (FY14-1,446).
    - The number of reports involving the release of a product that was not documented or incorrectly documented as issued in the computer, which was the only method of documenting the visual and clerical checks at the time of distribution, decreased 9% (FY14-747).
    - The number of reports involving the product not irradiated as required decreased from 169 in FY14 to 157 in FY15.
- The number of reports involving testing that was not performed, incompletely performed, or documented decreased from 203 in FY14 to 180 in FY15.

**Most Frequent BPD Reports - Quality Control & Distribution**
**From *Unlicensed Registered Blood Establishments***

Table 15

| QC & DISTRIBUTION (QC) 1,660 | # Reports | % of Total (QC) |
|---|---|---|
| ***Distribution procedures not performed in accordance with blood bank transfusion service's specifications*** | ***1,311*** | ***79.0%*** |
| Product not documented or incorrectly documented as issued in the computer | 681 | 41.0% |
| Product not irradiated as required | 157 | 9.5% |
| Improper product selected for patient | 139 | 8.4% |
| Improper ABO or Rh type selected for patient | 82 | 4.9% |
| Procedure for issuing not performed or documented in accordance with specifications | 73 | 4.4% |
| Product issued to wrong patient | 54 | 3.3% |
| ***Testing not performed, incompletely performed, or not documented*** | ***180*** | ***10.8%*** |
| Antigen screen | 50 | 3.0% |
| ABO and/or Rh | 45 | 2.7% |
| Antibody screen or identification | 39 | 2.3% |
| Compatibility | 27 | 1.6% |
| ***Distribution of product that did not meet specifications*** | ***140*** | ***8.4%*** |
| Product QC unacceptable, not performed, not documented or incomplete | 54 | 3.3% |
| Bacterial detection testing | 27 | 1.6% |
| Product in which instrument QC, calibration, or validation unacceptable, incomplete or not documented | 32 | 1.9% |
| Product in which specification other than QC not met | 21 | 1.3% |
| Outdated product | 21 | 1.3% |
| ***Shipping and storage*** | ***25*** | ***1.5%*** |
| Temperature not recorded or unacceptable upon return, unit redistributed | 9 | 0.5% |
| No documentation that product was shipped or stored at appropriate temperature | 8 | 0.5% |

*Note: All QC & distribution reports are not included in this table.*

Of the 3,093 reports (Table 7) submitted by unlicensed registered blood establishments, 727 (23.5%) involved **labeling** deviations or unexpected events (Table 16).

- The number of these reports decreased 6% (FY14-772).
- The number of reports involving the crossmatch tag, tie tag, or transfusion record labeled with incorrect or missing information decreased 9% (FY14-566).
    - The number of reports involving incorrect or missing recipient information on the crossmatch tag, tie tag, or transfusion record decreased from 163 in FY14 to 138 in FY15.
- The number of reports involving the unit labeled with incorrect or missing information was similar to the reports we received in the previous year (206 in FY14 compared to 211 in FY15).
    - The number of reports involving the expiration date extended or missing on the product label was similar to the reports we received in the previous year (90 in FY14 compared to 86 in FY15).
    - The number of reports involving the irradiation status incorrect or missing on the product label increased from 26 in FY14 to 33 in FY15.

**Most Frequent BPD Reports - Labeling**
**From *Unlicensed Registered Blood Establishments***

Table 16

| LABELING (LA) 727 | #Reports | % of Total (LA) |
|---|---|---|
| ***Crossmatch tag, tie tag, to transfusion record incorrect or missing information*** | ***516*** | ***71.0%*** |
| Crossmatch tags or transfused records switched, both units intended for the same patient | 144 | 19.8% |
| Recipient identification incorrect or missing | 138 | 19.0% |
| Crossmatch tag, tie tag, or transfusion record incorrect or missing or attached to incorrect unit | 59 | 8.1% |
| Expiration date or time extended or missing | 50 | 6.9% |
| Unit, lot, or pool number incorrect or missing | 32 | 4.4% |
| Product type or code incorrect or missing | 29 | 4.0% |
| ***Labels applied to blood unit or product incorrect or missing information*** | ***211*** | ***29.0%*** |
| Extended or missing expiration date or time | 86 | 11.8% |
| Irradiation status incorrect or missing | 33 | 4.5% |
| Product type or code incorrect or missing | 25 | 3.4% |
| Combination of incorrect or missing information | 17 | 2.3% |
| CMV status incorrect or missing | 14 | 1.9% |
| Donor/unit number or lot number incorrect or missing | 10 | 1.4% |

*Note: All labeling reports are not included in this table.*

Of the 3,093 reports (Table 7) submitted by unlicensed registered blood establishments, 313 (10.1%) reports involved **post donation information** (Table 17)**.**

- The number of these reports decreased 14% (FY14-366).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history decreased from 340 in FY14 to 300 in FY15.
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a malarial risk area decreased from 143 in FY14 to 86 in FY14.
    - The number of reports in which a donor or third party provided subsequent information regarding travel to a vCJD risk area increased from 54 in FY14 to 82 in FY15.
- The number of reports in which a donor or third party provided subsequent information related to post donation illness decreased from 17 in FY14 to 8.

**Most Frequent BPD Reports - Post Donation Information**
**From *Unlicensed Registered Blood Establishments***

Table 17

| POST DONATION INFORMATION (PD) 313 | # Reports | % of Total (PD) |
|---|---|---|
| ***Behavior/History*** | ***300*** | ***95.8%*** |
| Travel to malaria endemic area/history of malaria | 86 | 27.5% |
| Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) – travel | 82 | 26.2% |
| Donor received tattoo and/or piercing | 22 | 7.0% |
| Male donor had sex with another man | 17 | 5.4% |
| ***Illness*** | ***8*** | ***2.6%*** |
| ***Testing**** | ***4*** | ***1.3%*** |

*Includes testing positive for viral marker prior to donation at another location
*Note: All post donation information reports are not included in this table.*

Of the 3,093 reports (Table 7) submitted by unlicensed registered blood establishments, 236 (7.6%) reports involved **routine testing** deviations or unexpected events (Table 18)**.**

- The number of these reports decreased 21% (FY14-297).
- The number of reports involving testing performed, interpreted or documented incorrectly decreased from 167 in FY14 to 123 in FY15.
- The number of reports involving sample identification was similar to the reports we received in the previous year (68 in FY14 compared to 66 in FY15).
- The number of reports involving unacceptable reagent QC or the use of expired reagents decreased from 61 in FY14 to 47 in FY15.

**Most Frequent BPD Reports - Routine Testing**
**From *Unlicensed Registered Blood Establishments***

Table 18

| ROUTINE TESTING (RT) 236 | # Reports | % of Total (RT) |
|---|---|---|
| ***Testing performed, interpreted, or documented incorrectly*** | ***123*** | ***52.1%*** |
| Compatibility | 53 | 22.5% |
| Antibody screening or identification | 36 | 15.3% |
| Antigen typing | 21 | 8.9% |
| ABO and/or Rh | 8 | 3.4% |
| ***Sample (used for testing) identification*** | ***66*** | ***28.0%*** |
| Incorrect sample tested | 33 | 14.0% |
| Unsuitable sample used for testing (e.g., too old) | 13 | 5.5% |
| Sample used for testing was incorrectly or incompletely labeled | 12 | 5.1% |
| ***Reagent QC unacceptable or expired reagents used*** | ***47*** | 19.9% |
| Antibody screening or identification | 13 | 5.5% |
| ABO and/or Rh | 11 | 4.7% |
| Hemoglobin S testing | 8 | 3.4% |
| Antigen typing | 7 | 3.0% |
| Multiple testing | 2 | 0.8% |

*Note: All routine testing reports are not included in this table.*

## *C. Most Frequent BPD Reports Submitted by Transfusion Services*

Of the 1,826 reports (Table 7) submitted by transfusion services, 1,073 (61.8%) reports involved **quality control and distribution** deviations or unexpected events (Table 19).

- The number of these reports increased 3% (FY14-1,043).
- The number of reports involving distribution procedures not performed in accordance with the blood bank transfusion service's specifications decreased 7% (FY14-805).
    - The number of reports involving the release of a product that was not documented or incorrectly documented as issued in the computer, which was the only method of documenting the visual and clerical checks at the time of distribution, decreased 7% (FY14-356).
- The number of reports in which testing was not performed, incompletely performed, or not documented increased 28% (FY14-178).
    - The number of reports in which antibody screening was not performed, incompletely performed or not documented increased from 42 in FY14 to 72 in FY15.

**Most Frequent BPD Reports - Quality Control & Distribution**
**From *Transfusion Services***

Table 19

| QC & DISTRIBUTION (QC) 1,073 | # Reports | % of Total (QC) |
|---|---|---|
| ***Distribution procedures not performed in accordance with blood bank transfusion service's specifications*** | ***745*** | ***69.4%*** |
| Product not documented or incorrectly documented as issued in the computer | 332 | 30.9% |
| Product not irradiated as required | 96 | 8.9% |
| Procedure for issuing not performed or documented in accordance with specifications | 84 | 7.8% |
| Improper product selected for patient | 65 | 6.1% |
| Improper ABO or Rh type selected for patient | 53 | 4.9% |
| ***Testing not performed, incompletely performed, or not documented*** | ***228*** | ***21.2%*** |
| ABO and/or Rh | 72 | 6.7% |
| Antibody screen or identification | 56 | 5.2% |
| Antigen screen | 54 | 5.0% |
| Compatibility | 36 | 3.4% |
| ***Distribution of product that did not meet specifications*** | ***58*** | ***5.4%*** |
| Outdated product | 30 | 2.8% |
| Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented | 14 | 1.3% |
| ***Shipping and storage*** | ***39*** | ***3.6%*** |
| No documentation that product was shipped or stored at appropriate temperature | 13 | 1.2% |
| Stored at incorrect temperature | 10 | 0.9% |
| Product not packed in accordance with specifications or not documented that product was packed appropriately | 8 | 0.7% |
| Temperature not recorded or unacceptable upon return, unit redistributed | 8 | 0.7% |

*Note: All QC & distribution reports are not included in this table.*

Of the 1,826 reports (Table 7) submitted by transfusion services, 424 (24.4%) reports involved **labeling** deviations or unexpected events (Table 20)**.**

- The number of these reports increased 7% (FY14-397).
- The number of reports involving the crossmatch, tie tag, or transfusion record labeled with incorrect or missing information increased from 343 in FY14 to 359 in FY15.
- The number of reports involving the unit labeled with incorrect or missing information increased from 54 in FY14 to 64 in FY15.

**Most Frequent BPD Reports - Labeling**
**From *Transfusion Services***

Table 20

| LABELING (LA) 424 | # Reports | % of Total (LA) |
|---|---|---|
| ***Crossmatch tag, tie tag or transfusion record incorrect or missing information*** | ***359*** | ***84.7%*** |
| Crossmatch tags or transfused records switched, both units intended for the same patient | 91 | 21.5% |
| Recipient identification incorrect or missing | 89 | 21.0% |
| Product type or code incorrect or missing | 37 | 8.7% |
| Unit, lot, or pool number incorrect or missing | 35 | 8.3% |
| Crossmatch tag or tie tag missing or attached to incorrect unit | 28 | 6.6% |
| Expiration date or time extended or missing | 22 | 5.2% |
| ***Labels applied to blood unit or product incorrect or missing information*** | ***64*** | ***15.1%*** |
| Extended or missing expiration date or time | 39 | 9.2% |
| Product type/code and expiration date incorrect or missing | 11 | 2.6% |

*Note: All labeling reports are not included in this table.*

Of the 1,826 reports (Table 7) submitted by transfusion services, 326 (18.8%) reports involved **routine testing** deviations or unexpected events (Table 21)**.**

- The number of these reports increased 12% (FY14-292).
- The number of reports involving testing performed, interpreted or documented incorrectly increased from 180 in FY14 to 199 in FY15.
- The number of reports involving sample identification decreased from 72 in FY14 to 58 in FY15.
    - The number of reports involving incorrectly or incompletely labeled samples used for testing decreased from 53 in FY14 to 38 in FY15.
- The number of reports involving unacceptable reagent QC or the use of expired reagents increased from 40 in FY14 to 69 in FY15.

**Most Frequent BPD Reports - Routine Testing**
**From *Transfusion Services***

Table 21

| ROUTINE TESTING 326 | # Reports | % of Total (RT) |
|---|---|---|
| ***Testing performed, interpreted, or documented incorrectly*** | ***199*** | ***61.0%*** |
| Compatibility | 83 | 25.5% |
| Antibody screening or identification | 54 | 16.6% |
| Antigen typing | 29 | 8.9% |
| ABO and/or Rh typing | 21 | 6.4% |
| ***Sample (used for testing) identification*** | ***58*** | ***17.8%*** |
| Sample used for testing was incorrectly or incompletely labeled | 38 | 11.7% |
| Unsuitable sample used for testing | 16 | 4.9% |
| Incorrect sample tested | 4 | 1.2% |
| ***Reagent QC unacceptable or expired reagents used*** | ***69*** | ***21.2%*** |
| Multiple testing | 20 | 6.1% |
| ABO and/or Rh typing | 18 | 5.5% |
| Antibody screening or identification | 15 | 4.6% |
| Antigen typing | 14 | 4.3% |

*Note: All routine testing reports are not included in this table.*

## *D. Most Frequent BPD Reports Submitted by Licensed Plasma Establishments*

Of the 22,194 reports (Table 7) submitted by licensed plasma establishments, 18,942 (85.3%) involved **post donation information** (Table 22)**.**

- The number of these reports decreased 5% (FY14-20,007).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history decreased 5% (FY14-18,772).
    - The number of reports in which the donor had a history of a tattoo and/or piercing decreased 3% (FY14-13,303).
    - The number of reports in which the donor had a history of incarceration decreased 8% (FY14-826).
    - The number of reports in which the donor had non-sexual exposure to hepatitis (Hepatitis B or Hepatitis C) decreased 46% FY14-1,001.
        - Non-sexual exposure to Hepatitis B: FY14-220; FY15-124
        - Non-sexual exposure to Hepatitis C: FY14-781; FY15-413
- The number of reports in which a donor or third party provided subsequent information related to testing by another facility was similar to the number of reports received in the previous year (1,128 in FY14 compared to 1,122 in FY15).
    - The number of reports in which the donor tested positive by another facility, but the specific testing was unknown, was similar to the number of reports received in the previous year (1,119 in FY14 compared to 1,116 in FY15).

**Most Frequent BPD Reports - Post Donation Information**
**From *Licensed Plasma Establishments***

Table 22

| POST DONATION INFORMATION (PD) 18,942 | # Reports | % of Total (PD) |
|---|---|---|
| ***Behavior/History*** | ***17,710*** | ***93.5%*** |
| Donor received tattoo and/or piercing | 12,975 | 68.5% |
| Positive drug screen | 925 | 4.9% |
| Incarcerated | 844 | 4.5% |
| Non-sexual exposure to Hepatitis C | 413 | 2.2% |
| IV drug use | 410 | 2.2% |
| Other; unacceptable address, donor unreliable | 313 | 1.7% |
| ***Testing**** | ***1122*** | ***5.9%*** |
| Tested reactive at another center, specific testing unknown | 1116 | 5.9% |
| ***Illness*** | ***86*** | ***0.5%*** |
| Post donation diagnosis or symptoms of Hepatitis C, or reactive test for Hepatitis C | 30 | 0.2% |
| Post donation illness (not hepatitis, HIV, HTLV-I, STD, cancer, or cold/flu related) | 26 | 0.1% |
| Post donation diagnosis or symptoms of HIV, or reactive test for HIV | 19 | 0.1% |

*Includes testing positive for viral marker prior to donation at another location
*Note: All post donation information reports are not included in this table.*

Of the 22,194 reports (Table 7) submitted by licensed plasma establishments, 2,520 (11.4%) reports involved **miscellaneous** deviations or unexpected events (Table 23).

- The number of these reports was similar to the number of reports received in the previous year (2,523 in FY14 compared to 2,520 in FY15).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HCV increased 2% (FY14-1,643).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HBV decreased 12% (FY14- 578).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HIV increased 7% (FY14-296).

**Most Frequent BPD Reports - Miscellaneous**
**From *Licensed Plasma Establishments***

Table 23

| MISCELLANEOUS (MI)<br>2,520 | # Reports | % of Total (MI) |
|---|---|---|
| ***Lookback; subsequent unit tested confirmed positive for:*** | ***2,520*** | ***100.0%*** |
| HCV | 1,677 | 66.5% |
| HBV | 508 | 20.2% |
| HIV | 316 | 12.5% |
| Multiple markers | 19 | 0.8% |

*Note: All miscellaneous reports are not included in this table.*

Of the 22,194 reports (Table 7) submitted by licensed plasma establishments, 567 (2.6%) involved **quality control and distribution** deviations or unexpected events (Table 24)**.**

- The number of these reports increased 55% (FY14-367).
- The number of reports involving the distribution of a product with a positive test increased from 216 in FY14 to 433, specifically for donors testing positive for atypical antibodies.
- The number of reports involving the distribution of a product in which testing was not performed, incompletely performed, or not documented decreased from 92 in FY14 to 66 in FY15.

**Most Frequent BPD Reports - Quality Control & Distribution**
**From *Licensed Plasma Establishments***

Table 24

| QC & DISTRIBUTION (QC) 567 | # Reports | % of Total (QC) |
|---|---|---|
| ***Positive testing for*** | ***433*** | ***76.4%*** |
| Antibody screen or identification | 431 | 76.0% |
| ***Testing not performed, incompletely performed or not documented for*** | ***66*** | ***11.6%*** |
| Syphilis | 58 | 10.2% |
| Antibody screen or identification | 7 | 1.2% |
| ***Failure to quarantine unit due to medical history*** | ***50*** | ***8.8%*** |
| Donor received tattoo and/or piercing | 15 | 2.6% |
| Non-sexual exposure to Hepatitis C | 8 | 1.4% |
| ***Distribution of product that did not meet specifications*** | ***17*** | ***3.0%*** |
| Product identified as unsuitable due to a donor screening deviation or unexpected event | 6 | 1.1% |
| Product identified as unsuitable due to a collection deviation or unexpected event | 4 | 0.7% |

*Note: All QC & distribution reports are not included in this table.*

Of the 22,194 reports (Table 7) submitted by licensed plasma establishments, 145 (0.7%) reports involved **donor screening** deviations or unexpected events (Table 25).

- The number of these reports was similar to the number of reports submitted the previous year (144 in FY14 compared to 145 in FY15).
- The number of reports involving incomplete or incorrect donor records was similar to the number of reports to the previous year (54 in FY14 compared to 55 in FY15).
- The number of reports involving donors who did not meet acceptance criteria was the same as the previous year (FY14-46).
- The number of reports in which the donor gave a history that warranted deferral or follow up and was not deferred or follow up questions were not asked, decreased from 27 in FY14 to 20 in FY15.

**Most Frequent BPD Reports - Donor Screening**
**From *Licensed Plasma Establishments***

Table 25

| DONOR SCREENING (DS) 145 | # Reports | % of Total (DS) |
|---|---|---|
| ***Donor record incomplete or incorrect*** | ***55*** | ***37.9%*** |
| Donor identification | 27 | 18.6% |
| Donor history questions | 20 | 13.8% |
| ***Donor did not meet acceptance criteria*** | ***46*** | ***31.7%*** |
| Unacceptable address or no proof of address | 25 | 17.2% |
| Medical review or physical not performed or inadequate | 17 | 11.7% |
| ***Deferral screening not done or incorrectly performed, including incorrect ID used during search*** | ***20*** | ***13.8%*** |
| Donor previously deferred due to history | 18 | 12.4% |
| Donor previously deferred due to testing | 2 | 1.4% |
| ***Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked*** | ***20*** | ***13.8%*** |
| Donor received tattoo and/or piercing | 8 | 5.5% |
| Donor received medication or antibiotics | 4 | 2.8% |

*Note: All donor screening reports are not included in this table.*

## III. BPD Reports Submitted by Manufacturers of Licensed Biological Products Other Than Blood and Blood Components (Licensed Non-Blood)

Licensed non-blood manufacturers submitted 40 fewer reports in FY15 than in the previous fiscal year (FY14-598) (Table 2).

- Allergenic manufacturers submitted 5 fewer reports (FY14-87) (Table 5).
    - The number of reports involving product not meeting specifications, decreased from 81 in FY14 to 69 in FY15. The majority (88%) related to precipitate discovered in allergenic extracts, which decreased from 76 in FY14 to 61 in FY15.
- Blood derivative manufacturers submitted 14 more reports (FY14-109) (Table 5).
    - The number of reports related to process controls was similar to the number of reports to the previous year (31 in FY14 compared to 27 in FY15).
        - The number of reports related to process/procedures not performed or performed incorrectly decreased from 25 in FY14 to 14 in FY15.
        - The number of reports in which manufacturing or processing was performed using incorrect parameters increased from two in FY14 to 10 in FY15.
    - The number of reports related to product specifications was similar to the number of reports to the previous year (33 in FY14 compared to 35 in FY15).
        - The number of reports involving product specification not met for appearance increased from five in FY14 to 11 in FY15.
        - The number of reports involving the specification of a component packaged with a final product not met was similar to the number of reports to the previous year (15 in FY14 compared to 17 in FY15).
- Licensed in-vitro diagnostic manufacturers submitted 17 fewer reports (FY14-128) (Table 5).
    - The number of reports related to the product specifications decreased from 76 in FY14 to 66 in FY15.
        - The number of reports related to leaking vial or container due to loose or unsecure closures decreased from 19 in FY14 to 11 in FY15.
        - The number of reports related to the fill volume specification not met decreased from 10 in FY14 to zero in FY15.
        - The number of reports related to unexpected reactions in testing increased from 32 in FY14 to 43 in FY15.
    - The number of reports related to quality control and distribution were similar to the number of reports received in the previous year (19 in FY14 compared to 20 in FY15). The number of reports related to the consignee receiving products upside down or sideways within the shipping container was the same as the previous year (seven).

- Vaccine manufacturers submitted 24 fewer reports (FY14-247) (Table 5).
    - The number of reports involving product specifications decreased from 84 in FY14 to 74 in FY15.
        - The number of reports involving product not meeting specifications decreased from 57 in FY14 to 47 in FY15. Most of these were related to appearance (FY14-39, FY15-37).
        - The number of reports involving stability failures increased from 15 in FY14 to 21 in FY15.Most of these were related to potency (FY14-9, FY15-8) or chemical analysis/purity (FY14-0, FY15-5).
    - The number of reports involving quality control and distribution decreased from 48 in FY14 to 30 in FY15.
        - The number of reports involving broken or cracked vials decreased from 41 in FY14 to 23 in FY15.
    - The number of reports involving testing increased from 36 in FY14 to 43 in FY15, and were specifically related to stability testing performed incorrectly (FY14-20, FY15-26)
- Licensed HCT/P manufacturers (351 HCT/Ps) submitted eight fewer reports (FY14-27) (Table 5).
    - The number of reports related to the labeling controls decreased from 15 in FY14 to eight in FY15. Most of these involved the product labeled with the incorrect recipient identification (FY14-11, FY15-5).
    - There was one report submitted by an HPC, Cord Blood manufacturer, which involved a product labeled with an extended expiration date.

**Total BPD Reports by Manufacturing System**
**Licensed Non-Blood Establishments**
**FY15**

Table 26

| Manufacturing System | Allergenic | Blood Derivative | In Vitro Diagnostic | Vaccine | 351 HCT/P | TOTAL | |
|---|---|---|---|---|---|---|---|
| Product Specifications | 69 | 35 | 66 | 74 | 8 | 252 | 45.2% |
| Testing | 4 | 23 | 3 | 43 | 2 | 75 | 13.4% |
| Quality Control & Distribution | 0 | 22 | 20 | 30 | 0 | 72 | 12.9% |
| Process Controls | 2 | 27 | 3 | 20 | 1 | 53 | 9.5% |
| Labeling | 6 | 2 | 14 | 22 | 8 | 52 | 9.3% |
| Miscellaneous | 0 | 7 | 1 | 20 | 0 | 28 | 5.0% |
| Incoming Material | 1 | 7 | 4 | 14 | 0 | 26 | 4.7% |
| ***Total*** | **82** | **123** | **111** | **223** | **19** | **558** | 100% |

## IV. HCT/P Deviation Reports Submitted by Manufacturers of 361 HCT/Ps

The deviation reporting requirement for HCT/Ps regulated solely under section 361 of the PHS Act and 21 CFR Part 1271 became effective on May 25, 2005. HCT/Ps means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue[4] [21 CFR 1271.3(d)]. An HCT/P is regulated solely under Section 361 of the PHS Act and the regulations under 21 CFR Part 1271 if it meets all of the following criteria under 21 CFR 1271.10(a):

(1) The HCT/P is minimally manipulated;
(2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
(3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; **AND**
(4) Either:
    i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; **OR**
    ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function**, AND**:
        (a) Is for autologous use;
        (b) Is for allogeneic use in a first or second-degree relative**; OR**
        (c) Is for reproductive use.

The following is a summary of HCT/P deviation reports submitted by manufacturers of 361 HCT/Ps during FY15. The summary does not provide individual product type specifics, but only by cellular (e.g., hematopoietic stem/progenitor cells) or tissue (e.g., skin, musculoskeletal, cornea) products.

[4] HCT/P Deviation reporting applies to nonreproductive HCT/Ps.

Manufacturers of 361 HCT/Ps submitted 45 fewer reports in FY15 than in the previous fiscal year (FY14-301) (Table 2).

- There were 12 fewer reports involving cellular HCT/Ps submitted than in the previous fiscal year (FY14-146, FY15-134) (Table 6).
    - The number of reports involving processing and process controls was similar to the number of reports to the previous year (76 in FY14 compared to 71 in FY15). The number of reports involving contamination or potential contamination during processing was similar to the number of reports to the previous year (74 in FY14 compared to 71 in FY15).
    - The number of reports involving receipt, pre-distribution, shipment and distribution decreased from 57 in FY14 to 48 in FY15. The number of reports involving distribution of product that was contaminated or potentially contaminated decreased from 55 in FY14 to 45 in FY15.
- There were 33 fewer reports involving tissue HCT/Ps submitted than in the previous fiscal year (FY14-155, FY15-122) (Table 6).
    - The number of reports involving donor eligibility decreased from 61 in FY14 to 39 in FY15.
        - There were 22 fewer reports involving the acceptance of ineligible donors (FY14-61, FY15-39). In FY15, 30 of these reports involved risk factors, clinical or physical evidence identified, and six reports involved incorrectly evaluating or not evaluating the donor for plasma dilution.
    - The number of reports involving donor screening was similar to the number of reports received in the previous year (31 in FY14 compared to 35 in FY15).
        - The number of reports in which the donor medical history interview was performed incorrectly was similar to the number of reports received in the previous year (12 in FY14 compared to 16 in FY15).
    - The number of reports involving donor testing was similar to the number of reports received in the previous year (7 in FY14 compared to 9 in FY15).
        - The number of reports involving unacceptable samples used for testing was similar to the number of reports received in the previous year (4 in FY14 compared to 5 in FY15).
    - The number of reports involving receipt, pre-distribution, shipment and distribution was similar to the number of reports received in the previous year (22 in FY14 compared to 21 in FY15).
    - The number of reports involving processing and processing controls decreased from 14 in FY14 to five in FY15.

**Total Reports by Manufacturing System**
**361 HCT/P Establishments**
**FY15**

Table 27

| HCT/P Deviation Code | Cellular HCT/P | Tissue HCT/P | Total | |
|---|---|---|---|---|
| Processing and Processing Controls | 71 | 5 | 76 | 29.7% |
| Receipt, Pre-Distribution, Shipment & Distribution | 48 | 21 | 69 | 27.0% |
| Donor Eligibility | 0 | 39 | 39 | 15.2% |
| Donor Screening | 0 | 35 | 35 | 13.7% |
| Donor Testing | 2 | 9 | 11 | 4.3% |
| Recovery | 7 | 3 | 10 | 3.9% |
| Supplies and Reagents | 6 | 1 | 7 | 2.7% |
| Labeling Controls | 0 | 5 | 5 | 2.0% |
| Storage | 0 | 4 | 4 | 1.6% |
| Environmental Control | 0 | 0 | 0 | 0.0% |
| Equipment | 0 | 0 | 0 | 0.0% |
| **Total** | 134 | 122 | 256 | 100% |

## V. Attachments

1 – Table-Number of BPD Reports by Type of Blood and Plasma Establishment
2 – List of BPD Codes for Blood and Plasma Establishments
3 – Table-Number of BPD Reports by Type of Licensed Non-Blood Establishment
4 – List of BPD Codes for Licensed Non-Blood Establishments
5 – Table-Number of HCT/P Deviation Reports by Type of 361 HCT/P Establishment
6 – List of HCT/P Deviation Codes for 361 HCT/P Establishments
7 – List of Tables

## VI. References


1. Guidance for Industry - Biological Product Deviation Reporting for Blood and Plasma Establishments 10/18/2006
   http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm073455.htm

2. Guidance for Industry - Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components 10/18/2006
   http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/ucm163893.htm

3. Draft Guidance for Industry - Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271 12/2015
   http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM478826.pdf